

REMARKS

A Request for a Two (2) Month Extension of Time pursuant to 37 CFR §1.136(a) and (b) is attached hereto.

The above-captioned patent application has again been carefully reviewed in light of the non-final Office Action to which this Amendment is responsive. Claims 1, 3-4, 6-14 and 74-78 have been amended in an effort to further clarify and distinctly describe the combination claimed herein.

Claims 1, 3, 4, 6-14 and 74-78 are pending. Each of the pending claims have been rejected in light of certain prior art. More particularly, Claims 1, 3, 4, 6-14 and 74-78 have been rejected under 35 USC §103(a) based on the combination of Jacobs et al. (U.S. Patent No. 5,846,492) in view of Corbett (WO 92/20778) and/or Samsoondar (WO 99/47261). Claims 1, 3, 4, 6-14 and 74-78 have also been rejected under 35 USC §103(a) based solely on Jacobs et al. (U.S. Patent No. 6,797,518). Claims 1, 3, 4, 6-14 and 74-78 have also been rejected under 35 USC §103(a) based on the combination of Jacobs et al. '518 and Samsoondar.

All pending Claims 1, 3, 6, 6-14 and 74-78 have also been rejected under 35 USC §112, 2nd paragraph, for indefiniteness issues. Applicant respectfully requests reconsideration based on the amended claims, as well as the following discussion.

As to the prior art rejections, in order to successfully maintain a "*prima facie*" obviousness rejection under the Statute, each and every claimed limitation must be found in or suggested by the prior art. Those limitations that are not either found in the prior art or suggested thereby must be notoriously well known to those of ordinary skill in the field of the invention. In terms of combining references, there must also be a motivation found in the prior art as a whole to make the purported combination. This combination cannot be through advance knowledge (i.e., hindsight) of the present invention.

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As to the first above-noted prior art rejection, the Examiner believes (see page 7 of the pending Office Action) that Jacobs '492 teaches all of the features of independent Claim 1 with the exception of a sample handler for holding sealed tips and a plurality of stations to place these stations. The Examiner relies upon either of the secondary references to Corbett and/or Samsoondar for teaching the placement of plural tips in plural holders for passage through a measurement station. More specifically, the Examiner has characterized Samsoondar as a blood analyzer having sample handling means (94) carrying sealable tips (1, 2) in stations (90), sealing means (5), a spectrophotometer (14) and smaller tips for insertion into the sealable tips. According to the Examiner, the stations of each of Samsoondar and Corbett are structurally capable of carrying either sealed or unsealed tips and therefore satisfy the limitations to first and second pluralities of tip retaining stations. Therefore, it would have been obvious to one of ordinary skill to have included the Jacobs et al. apparatus for the pipette tip of Corbett or Samsoondar to provide known sealing means and conveyance in place of air pressure to maintain liquid in a pipette tip for measurement and/or reaction.

Jacobs '492 illustrates, as shown in Fig. 1, a dispense station 18 that includes apparatus 46 that receives a disposable tip 48 for aspirating a quantity of sample from one of a plurality of sample containers 19 circumferentially disposed on a tray 20. The disposable tips 48 used in conjunction with the aspirating process are provided on an inner circumferential portion of the tray 20. As described therein, a tip is received by the metering apparatus 40 and more specifically a tip held in relation to the probe 46 with air pressure applied by means of a pump 71.

Once fluid (i.e., sample) has been aspirated from one of the containers 19, the tip is moved into position relative to a test station and the sample liquid is then dispensed onto a dry slide element E in relation to an incubator. The tip can then be sealed and placed into a test station and more particularly in relation to a scanning block that spectrophotometrically analyzes the patient fluid.

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This reference, however, does not describe apparatus that asynchronously operates between two or more chemistry systems of an analyzer. More particularly, this cited reference fails to teach or describe an auxiliary sample handler that coordinates the independent operation of at least two chemistry systems. The sample handler utilized by Jacobs '492 (that is, containers 19) is a primary sample handling device. No other source of sample is described, other than the tips that receive patient fluid from the sample containers. The tips' only other "function" according to this disclosure is that of having its contents scanned. There is no discussion or teaching wherein a disposable tip actually becomes a second sample supply. In essence, Jacobs '492 provides a teaching of conventional so called "dry slide" analyzers, in which the analyzer is further equipped for "through the tip" optical sample analyzers. To that end, this reference fails to describe or suggest an analyzer having both a primary and a secondary or auxiliary sample handler. In addition and as acknowledged by the Examiner, this reference fails to describe any teaching relating to sealed tips, their use as sample containers. The Examiner has regarded the optical testing of the tip as a second analytical system. It is respectfully submitted, that in spite of this interpretation, this reference also fails to discuss or describe an apparatus having any relationship between at least chemistry, such as a wet chemistry system and a dry chemistry system as those found in a combinational clinical analyzer.

Turning to the secondary references, Corbett illustrates a device used for reaction control in conjunction with polymerized chain reaction (PCR) testing. This device includes an incubator having concentric rings in which a plurality of outer wells receive pipette tips and samples are contained in the pipette tips by sealing a lower end of the tip. This reference utilizes the sample tip as a reaction vessel wherein the incubator is used to heat and/or cool the tips containing sample. As noted in this reference "...there is no transfer of sample to a sample container for reaction". As such, the sealed disposable tips described by Corbett are not utilized as an auxiliary sample holder, but rather are treated no differently than any reaction vessel, such as, for example, a dry slide element as described by Jacobs et al. '492. Sample is not removed from the tip for other purposes, such as for aspirating purposes in conjunction with a second chemistry system of the analyzer. In addition, Corbett fails to teach or

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describe a second plurality of unsealed metering tips that are used in conjunction with two different chemistry systems of the analyzer to permit asynchronous operation. That is, neither Jacobs '492 or Corbett teaches or suggests that a stored plurality of unsealed metering tips can be used to both aspirate patient sample for dispensing a portion of the sample in connection with a first chemistry system and also be used in connection with a second chemistry system of the analyzer to aspirate a volume of fluid and dispense the volume of fluid into a reaction vessel of a second separate chemistry system.

Samsoondar describes a method and process by which "through the tip" optical measurements can be made using a disposable metering tip. In this disclosure, the tip is sealed and it is further observed that the tip can receive reagents using a second tip that is capable of being inserted into the first sealed tip "for adding one or more reagents to the disposable metering tip". Following receipt of all of the above-noted fluids, the tip is placed in relation to a radiation source that is sensed to correlate the concentrations of one or more proteins in the sample. As such, the sealed metering tip is simply used a reaction vessel. No teaching is provided or suggested that the sealed metering tip can be utilized as an auxiliary sample container and therefore used in lieu of the primary sample containers of the analyzer. In addition, this reference also fails to describe or suggest any structure for an auxiliary sample handler that employs pluralities of both sealed and unsealed metering tips for asynchronous operation with a clinical analyzer. The Samsoondar reference only describes a conveyor setup with sealed metering tips.

Therefore, none of these above cited references utilize or teach the use of a sealed disposable metering tip, other than as a reaction vessel or a test vessel. There is no teaching, explicit or inferred, in which a plurality of sealed disposable metering tips containing patient samples are used as an auxiliary sample supply, and in which sample is aspirated from the sealed metering tips for use in dispensing fluid into a reaction vessel of the analyzer. In addition, there is no teaching, suggestion or other inference from any of the above references to utilize a structure wherein a plurality of

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unsealed metering tips are used in conjunction with a metering mechanism to aspirate liquid and dispense same for at least two different chemistry systems of a clinical analyzer.

Claim 1 has now been further amended to clarify the above features. More particularly, Applicant herein amends Claim 1 to specify that a portion of the plurality of unsealed metering tips are used in conjunction with a metering mechanism to aspirate a volume of patient sample from the primary sample supply of the analyzer and to then dispense a portion of the patient sample to a reaction vessel of a first chemistry system prior to sealing a dispense end of the tip. As a result, the plurality of sealed metering tips are created. The remaining sample retained within the now-sealed metering tip can then be aspirated therefrom using a metering mechanism and dispensed onto a reaction vessel of a second separate chemistry system of the analyzer. Another portion of the plurality of unsealed metering tips are used to aspirate a fluid, such as a reagent, onto the reaction vessel of the second chemistry system. Support is found for each of the foregoing amendments in the present specification. For example, the Examiner is asked to refer to page 12, line 20 – page 17, line 13. Nowhere does any of Jacobs '492, Corbett and/or Samsoondar, alone or in combination, teach or describe the above features nor is there any suggestion to provide such teachings. In fact, reading the cited references in their entirety, as is required, would provide a contrary teaching in that Corbett and Samsoondar each require that the sealed tips be utilized only as reaction vessels and not as sample supplies or containers. As a result, it is believed this rejection of Claim 1 should be withdrawn. Claims 3-4, 6-14, 74-78 should be allowed over these references for the same reasons.

With regard to the rejection of Claims 1, 3, 4, 6-14 and 74-78 based on Jacobs et al. '518, taken alone or in combination with Samsoondar, Applicant discusses as follows. The sole independent claim in the above-captioned application is Claim 1. Jacobs '518 describes the use of "through the tip" optical analysis in a clinical analyzer wherein it is noted briefly (see col. 7, lines 44-52) that a sealed tip may further be used as an auxiliary sample container. Applicant notes, however, that this reference fails to describe all of the salient features of the presently claimed invention. That is, the

present analyzer includes an auxiliary sample handler that includes a plurality of unsealed metering tips as well as a plurality of sealed metering tips. As now recited in amended Claim 1, a portion of the plurality of unsealed metering tips are used to aspirate fluid from a primary sample supply for use with a first chemistry system of the analyzer and another portion of the unsealed metering tips provide a tip supply for aspirating reagent or other fluids for dispensing onto a reaction vessel of a second chemistry system. As to the use of the unsealed metering tips with the first chemistry system, a portion of the aspirated volume is dispensed onto a reaction vessel of the first system and the sample remaining in the tip is utilized by sealing the dispense end, thereby creating one of the sealed metering tips. The now-sealed metering tip is then used a sample container for the second chemistry system wherein sample can be aspirated from the tip for dispensing onto a reaction vessel of the second chemistry system. In one embodiment, the first chemistry system is a dry chemistry system and the second chemistry system is a wet chemistry system. As such, the herein claimed auxiliary sample handler is multi-functional and enables asynchronous operation of a multi-system or combinational clinical analyzer. Though Samsoondar does describe an automated conveyor 94, it does not describe a clinical analyzer or a structure like that of Applicants. Likewise, Corbett does not illustrate unsealed metering tips as part of their arrangement. None of the prior art describes or suggest the present combination. Jacobs '418 illustrates unsealed tips used in conjunction with a single (dry) chemistry system and primary sample cuvettes used in conjunction with the unsealed tips on a single structure.

As a result, we believe Claims 1, 3, 4, 6-14 and 74-78 are patentably distinct from the prior art since none of the above prior art cited by the Examiner includes or suggests all of the features now included in independent Claim 1. Reconsideration is therefore respectfully requested.

As to the Section 112 rejections, Applicant has now amended each of the dependent claims to specify the combination properly from Claim 1. Claim 1 has been amended as suggested by the Examiner to replace "within" as "and" in line 2. Claims 74, 75 and 77 have also been amended to handle clarity issues noted by the Examiner. It is now believed the claims are in an allowable condition.

In summary and in view of the above amendment, Applicant believes the above-captioned application is now in a condition for allowance and an expedited Notice of Allowability is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, she is invited to contact Applicant's representative at the telephone number below.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0289, under Order No. 961_006RCE from which the undersigned is authorized to draw.

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Respectfully submitted,

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